

# **REMARKS**

This letter is responsive to an Advisory Action mailed January 09, 2004. The applicant hereby notifies the Examiner that he has elected to respond pro se.

# **REMARKS**

Sir:

In response to an Advisory Action mailed January 09, 2004 and telephonic communication of February 28, 2004, the applicant hereby notifies the Examiner that he has elected to respond pro se. A revocation of Power of Attorney is hereby enclosed.

In the Advisory Action, the Examiner finds that:

1) New material is rejected under 35 USC 132, including

“to a tissue”;

“contacts a tissue surface”;

“at least two elongate elements”;

“a wire”;

“against a tissue surface”;

“does not contact the tissue surface”;

“periphery height along the axis of the nut is equal to or less than the height of the band.”;

“one or more prongs ... contact a tissue”;

“natural dissolution period... and an inducible dissolution period”;

“against the tissue”; and

“against the tissue surface”.

3) Typographical error

4) Claims 65, 72, 75, 76, 78, 80, 90, 91, 92, 93, 95, 99, 105, 106, 107, 108, 110, 112, 114 and 120-133 are rejected as being distinct inventions from the elected species.

6) Claim 74 is rejected as lacking antecedent basis for the limitation “the smaller diameter” and “the larger diameter”.

7) Claim 81 is rejected in that it contradicts claim 79 upon which it depends.

9) Claims 64, 66-71, 73, 74, 79, 81-89, 94, 96-98, 100-104 109, 111, 113, 115-119, and 134-137 are rejected under 35 U.S.C. 103(a) as being obvious over Seegmiller et al. in US Patent No. 5, 525, 013.

## **1. Incorporation by Reference**

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The instant application begins by citing a list of documents incorporated by reference, including: "U.S. Patent Application Serial No. 08/601,177, filed February 14, 1996, now U.S. Patent No. 6,162,234.

**A. Hard and Soft Tissue**

During the telephonic communication, the Examiner requested clarification of the tissues that the instant invention fastens.

Column 10, lines 7-9 states that the instant invention presents a "system for the fastening of a soft tissue—such as a tendon, or ligament, or joint capsule—to a hard tissue—such as a bone".

**B. Tissue Surface**

Column 3, lines 10-13 of US Patent 6,162,234, explains that in Figs. 32-24, the fastener presses against a tissue surface:

"... 'a sliding button cinch anchor' that brings a soft tissue toward the bone and then clamps against the shaft, holding the tissue in position through compression of a large surface area of tissue. "

The above quotes provide basis for the following claim language:

"to a tissue";  
 "contacts a tissue surface";  
 "against a tissue surface";  
 "against the tissue"; and  
 "against the tissue surface".

**C. Suture**

US Patent 6,162,234 shows Figs. 38-40 wherein shaft 111C1 comprises a suture, as explained in column 19, lines 52-56:

"Figs. 38-40 show still yet another new embodiment...so as to hold onto suture 111C1."

**D. Wire**

Examiner has objected to claims 67, 85, 97 and 114 that claim "wire", a standard form of suture. (See "monofilament suture" in Ethicon Suture (Johnson and Johnson) catalogue.)

As "wire" is included in "suture", claims 67, 85 and 97 have ample precedent in the instant application.

**E. Two Elongate Elements**

Examiner has objected to claims 65, 80, 95 and 110 claiming "two elongate elements". Applicant disagrees and respectfully points out that this embodiment is seen in Figs. 38-40 and explained on column 20, lines 5-8 of U.S. Patent No. 6,162,234:

"Because the suture it 111C1 can be considered to be an extension of the shaft 111C, both elements commence with identification "111C".

**D. Dissolvable**

Examiner has objected to basing claims 78, 93, 108, and 132 on a European Patent incorporated by reference. Applicant respectfully submits that the claims are well-supported by the text:

U.S. Patent No. 6,162,234, column 10, lines 1-4 states:

"Finally, it has discovered that a button cinch anchor fastener in accordance with the present invention may be constructed substantially, or entirely, from material(s) that are bio-absorbable."

The definition of "bioabsorbable" according to US Patent Subclass 606/154 is "Subject matter wherein the connector element is composed of disintegratable material which the body is capable of absorbing.

The Applicant respectfully submits that the bioabsorbable suture nut is the same material as described on page 6, lines 4 and 5 of the instant application:

"A novel method is shown in the patent whereby such dissolvable materials ... can be made to dissolve more rapidly when in contact with a catalytic agent."

**E. Prongs**

Examiner has objected to basing claims 77, 92, 107, 125 and 126 that claim "prongs" on a European Patent incorporated by reference.

To expedite acceptance of the instant application, Applicant hereby cancels claims 77, 92, 107, 125 and 126.

**F. Periphery height**

Examiner has objected to basing claims 72, 99 and 112 that claim "periphery height ... less than the height of the band." on a European Patent incorporated by reference.

To expedite acceptance of the instant application, Applicant hereby cancels claims 72, 99 and 112.

**G. Band Contacts Tissue**

Fig. 121 of the present invention shows band B in the lower position so that its bottom edge is in contact with a tissue and Fig. 130 shows band B in the upper position so that its bottom edge is not in contact with a tissue surface.

**3). Amendment of Specification**

Specification has been (previously) amended as above, changing the first R1 to R2, thereby correcting the typographical error.

**4). Distinct Inventions From The Elected Species**

Applicant respectfully cancels claims 72, 75-77, 81, 90-92, 99, 105-107, 112, 114 and 120-133 and reserves the right to enter these claims in a continuation application.

**6). Antecedent Language**

Examiner has objected to claim 74 for reciting the limitation of "the smaller diameter and "the larger diameter". Applicant respectfully disagrees. Page 47, lines 15-18 of the Instant Application states:

"In figure 121, the split suture nut SSN is depicted in partial section. The lower ramped surface R2 has an overall narrower diameter than the upper ramped surface R1, so that when the band B is around the Split Suture Nut SSN at the lower Ramp R2, the sections C1 and C2 are not compressed against the suture S."

**7) Claim 81**

To expedite acceptance of the instant application, Applicant hereby cancels claim 81.

**9) Obviousness over Seegmiller et al. - US Patent No. 5, 525, 013.**

Seegmiller et al. teach jaws that serve to compact or "crimp" together multiple strands

of an industrial cable, as seen in Fig. 13. A separate nut is used to contact bearing plate 87, as stated in column 8, lines 22-25:

"cable 45 being held in place by jaws 63 ... with nut 23, of course being positioned directly against bearing plate 78."

Another embodiment, shown in Figs. 20 and 21, show the jaws 63 around cable 80 while internal to cable sheath 107. As in all other embodiments, only nut 89 anchors cable 107 against plate 87.

In distinct contrast, the instant invention claims "An orthopedic fastening system ... for securing at least one elongate element to a tissue, the system comprising two or more nut section that assemble to form a nut".

Additionally, it is not obvious to even contemplate the use of Seegmiller et al. for "securing ... to a tissue", or anywhere near a tissue:

Seegmiller et al. teach a fastener that comprises metals that corrode during industrial use, but are substantially prevented from corroding through "the usage of epoxy-coated .. cable" (Column 1, lines 15-16) that retard corrosion of the cable.

A fastening system that "contacts a tissue" requires that *every* part of an implant, whether internal or a external, be non-corroding in the hostile body environment.

Clearly, Seegmiller et al. teaches a different device than the instant invention that could not be even contemplated for use in the in vivo environment.

Early and favorable consideration is earnestly solicited. In the event that the Examiner cannot issue a notice of allowance, please use the address listed below for sending correspondence to the applicant.

Respectfully submitted,

  
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